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OPTICAL EXAMINATION DEVICE, SYSTEM AND METHOD

Cross Reference To Related Applications

This application is a continuation-in-part of now pending PCT/US96/00235 filed 02 January 1996, which claims priority from U.S. Serial No.: 08/367,939 filed January 3, 1995, which claims priority from PCT/US95/15694 filed 04 December 1995, which claims priority from PCT/US95/15666, filed 04 December 1995. All of the foregoing are incorporated herein by reference.

Background of the Invention

Continuous wave (CW) spectrophotometers, time resolved (TRS/Pulse), phase modulation (PMS) and phased array spectrophotometers are all known to have application to medicine. These systems depend upon the ability to couple light into tissue from a light source and to couple light from the tissue to a spaced detector. The difference in the flash produced on the photon migration paltorn by abnormality and normal conditions in the body due to different scattering and absorption of the light produce effects that, in principle, enable the use of spectrophotometric examination of the brain is seen as particularly appropriate for the detection of abnormal conditions, in the brain, especially hematoma but also vascular conditions, tumor, and metabolic conditions. Likewise, examination of breast, testicle and muscle is appropriate.

For practical use in medicine, improvement in optical coupling to the subject, is needed to enable these types of spectrophotometric examination to be widely accepted for clinical or home use.

Summary of the Invention

According to one aspect of the invention, an input or output optical coupler device for transmitting photons between an optical source or detector and the brain, or other part of the body, comprises an array of optical fibers with end portions that freely protrude as cantilevers from a support in the manner of bristles from a hairbrush, the end regions of the fibers sized and distributed to penetrate freely extending hair on the head or other surface of the subject to make optical contact over an array of points with the surface of the skin or scalp, below the free hair.

Preferred embodiments of this aspect of the invention have one or more of the following features.

An examination device is associated with source and detector in which a set of optical fibers of the hairbrush transmits light to the scalp of a subject from the source, and a set of optical fibers of the hairbrush receives light from the scalp at known distance from the source fibers for transmission to the detector.

The fibers have smooth, enlarged tips that comfortably engage the skin or scalp.

The fibers are resiliently flexible laterally to bend and conform the pattern of fiber tips to variations in the shape of the skull, breast or other portion of the body.

The freely extending end portions of the fibers have a length to diameter ratio of between about 5 and 200. In preferred cases the ratio is between 20 and 150, while in other cases between 50 and 125.

The free end portions of the optical fibers have diameter of the order of 0.1 to 3.0 millimeter and have a length between about 0.5 to 3 cm.

The free end portions of the optical fibers have diameter of about 0.2 to 0.5 millimeter and length between about 1 and 2.5 cm.

The coupler device is constructed as a handheld probe, being sized and configured to be moved and placed against the front, sides and top of the head.

The coupler device is constructed as a handheld probe, being sized and configured to be moved and placed against the inside or outside surfaces of the breast.

The coupler device has fibers disposed in a two dimensional array, each fiber or small groupings of the fibers being associated with a discrete detector so that fiber tips simultaneously engage an area of the subject sufficient to provide data to enable processing to provide a back projection image.

One or a set of coupler devices, as part of a helmet or brassier, have sets of fibers arranged to simultaneously, or sequentially engage front, sides and top of the portion of the head or breast being examined.

In another aspect, the coupler is a conformable brush of fine fibers suitable to be applied to breast, testicles, arm or leg.

Other aspects of the invention comprise a hematoma detector or monitor, a tumor detector, a spectrophotometric imager or a metabolic condition monitor employing the brush coupler or other aspects of the devices shown.

Brief Description of the Drawing

Figs. 1 and 1A depict a "hairbrush" optical coupling system for optical examination of the brain.

Figs. 2 and 2A depict a "hairbrush" optical coupling system for optical and MRI examination.

Fig. 3 is a side view and Fig. 3A a bottom plan view of a "hairbrush" optical coupler suitable for monitoring;

Fig. 4 is a side view and Fig. 4A a bottom plan view of a "hairbrush" optical coupler suitable for optical imaging;

Fig. 5 illustrates use of a "hairbrush" coupler on the sides and frontal regions of the head; while

Fig. 5A illustrates use on the top of the head;

Fig. 6 illustrates a hat or helmet constructed to guide into position "hairbrush" optical coupling devices;

Fig. 6A is a cutaway view of the helmet of Fig. 6 illustrating the relationship of the "hairbrush" coupler to a subject with a large head of hair; while

Fig. 6B is an enlarged cross-sectional view of a portion of the device of Figs. 6 and 6A.

Figs. 7-11 depict stages in the application of protective end tips on protruding fiber portions of a "hairbrush" optical coupler;

Figs. 9A, 10A and 11A are magnified views of portions of the views of Figs. 9, 10 and 11, respectively;

Fig. 12 is a side cross-sectional view on magnified scale of an end tip for fibers of a coupling device;

Figs. 12A and 12B depict contrast members suitable for use in the end tip of Fig. 12;

Fig. 13 is an alternative construction of an end tip having provisions for receiving a band-form contrast member;

Fig. 13A is a perspective view of a band contrast member for use with the end tip of Fig. 13; while

Figs. 13B and 13C are cross-sections taken on line 13B of Fig. 13A illustrating cross-sections of two alternative contrast members for use with the end tip of Fig. 13;

Fig. 14 is a further embodiment of an end tip;

Figs. 15 and 16 depict optical coupling systems constructed for examination of breast tissue.

Description of the Preferred Embodiments

Referring to Fig. 1, an embodiment of a hairbrush optical coupler 70 is shown. This optical coupler is designed to provide optimal coupling of light to and from brain tissue in regions where the skull is covered by hair. Coupler 70 includes at least one source probe 72 and at least one detection probe 75. Source probe 72 is made of approximately twenty optical fibers of 0.5 millimeter to 3 millimeter in diameter and at least one half centimeter in length. Input ports 73 (i.e., irradiation tips) of the fibers of source probe 72 are arranged to form a selected structure (e.g., a matrix, mosaic, circular or linear structure) depending on the desired input geometry and the type of the examined tissue. Each irradiation tip of the fiber may include an optical matching material (e.g., a plastic, a gel-like material, a coating or the like) located between the fiber and the tissue and designed to introduce light efficiently into the examined tissue. At the proximal end, probe 72 has one or more light coupling ports 74. The probe has a single light coupling port made of the fibers bundled together and arranged to achieve efficient coupling of light from a light source (e.g., a light bulb, a light emitting diode, a laser) to the probe. Alternatively, the probe has multiple light coupling ports (e.g., one port per fiber), wherein the generated light is coupled into the fibers sequentially or simultaneously.

Detection probe 75 includes one or more detection ports 76 and one or more light coupling ports 77. Detection probe 75 has a similar design as source probe 72, but may have a larger number of individual fibers in order to collect a sufficient amount of light that has migrated in the tissue. At the proximal end, the detection fibers may also be bundled together to form a single light coupling

port 77, which provides good coupling to a wide area detector (e.g., a diode detector, a PMT detector or a MCPD detector). Since source probe 72 and detection probe 75 have a similar construction, they may be used interchangeably. Several source probes and detection probes may be coupled to an optical sequencer or multiplexer constructed to transmit and receive light in a desired manner. The probes are made of cladded fibers to eliminate crosstalk.

Source probe 72 and detection probe 75 are mounted on a support member constructed to achieve a selected position of the fibers and a desired separation of the input ports and the detection ports. The support member can also transmit pressure to the fiber tips for improved coupling of light to the tissue. A connected spectrophotometer (such as a TRS-pulse, PMS, CW, or phased array spectrophotometer) probes deep tissue at large separations of the ports (ϱ = 5 cm to 10 cm) and probes a dermal layer at small separations (ϱ = 0.5 cm to 2 cm).

The hairbrush optical coupler can be used for examination of symmetrical tissue regions of the brain, breast, arm, leg or other, as is described in the WO 92/20273 application. The hairbrush optical coupler can be also employed to detect asymmetrical tissue properties of optically symmetrical body regions. Fig. 1A depicts the hairbrush coupler attached to the head; specifically, to the parietal bones of a newborn which still has the characteristic opening called anterior fontanel. Input ports 73A and 73B of source probes 72A and 72B, respectively, are located on symmetrical locations of the corresponding parietal bones (or the temporal bones, the occipital bone, etc.). Detection ports 75A and 75B are spaced the same distance (ϱ, usually 3 cm to 8 cm) from the

corresponding input ports 73A and 73B. The spectrophotometer introduces radiation of a selected wavelength at each input port and detects radiation at each detection port. The spectrophotometer stores the detected data separately and correlates them together or with a stored data corresponding to the individual brain regions to identify any asymmetry in tissue properties. Alternatively, the spectrophotometer measures a differential signal directly. Normal tissue provides a substantially symmetrical signal. A detected asymmetry may be caused by a tissue disease, such as localized bleeding, an asymmetric stroke volume, or another pathological condition. (For example, see S.P. Gopinath et al., J. Neurosurg., 79, 1993.)

In another embodiment, a multifiber hairbrush probe is used for imaging of the brain. For this purpose, a series of semirigid 1 mm fibers is embedded in a styrofoam or plastic helmet. When the helmet is attached to the head, the input ports of the fibers project through the hair to the surface of the scalp. The patient's head is covered by, for example, 4 rows of 8 fibers extending from the frontal region to the occipital region. A larger number of fibers is used when a higher resolution of the image is needed. Each fiber is coupled at its optical coupling port to an optical sequencer or multiplexer. This way any fiber may be coupled to a light source or a light detector of an optical imager described in PCT/US93/05868 or PCT/US95/15694.

Referring to Fig. 2, in another embodiment, the hairbrush optical coupler is constructed for in vivo examination of tissue using simultaneously magnetic resonance imaging (MRI) and medical optical imaging (MOI). The coupler includes a styrofoam cap 85 with four rows of 8 fibers extending from frontal to occipital region of the patient's head 88 located inside an MRI magnet 90. The

optical fibers extend through the hair to the skull and may include ferrite caps. Each fiber is coupled at its optical coupling port to a fiber junction box 92. Fiber junction box 92, located outside of magnet 90, has appropriate electromechanical or electro-optical switches to time sequence the switching of a fiber conduit 91 to any one of the 32 fibers coupled to the head 88. The system employs any one or more fibers for transmission and any other fibers for detection. An MRI/MOI control center 94 includes an imaging center 95 and a computer system 96, which is constructed to create and overlay the optical and magnetic images. Coordination of the optical and MRI images is achieved by MRI/optical markers. Three-dimensional markers are formed by coating the fibers with a film exhibiting a magnetically relaxed water-like signal so that each optical fiber appears on an NMR image. This way an optical image generated by the corresponding source and detector fibers is correlated to the MRI image. Importantly, such "labeled" fibers do not interfere with the NMR examination.

Imaging center 95 employs a TRS system described in U.S. Pat. 5,119,815 or in U.S. Pat. 5,386,827. The TRS system includes a Ti sapphire tunable laser that generates a series of light pulses of different wavelengths in the NIR region, sensitive to an endogenous or exogenous pigment. The light pulses, generated as shown in a timing diagram of Fig. 2A, are transmitted via fiber conduit 91 to fiber junction box 92. At fiber junction box 92, the signals are multiplexed to the 32 fibers that transmit light to and receive light from appropriate places in the brain. A single optical fiber may also be connected to fiber branches which are attached to various places on the head. The TRS system also includes two 8 multi-anode micro-channel plate detectors. The detector output is sent to a parallel

computer that generates images congruent with the MRI scan and completed in approximately the same time as the MRI data.

To achieve proper coupling, the fibers are indexed in space to form an array and are encoded appropriately by an index pad that mimics the tissue positions. This identifies the position of the fibers in the array 1 through 32 relative to a master synchronizing pulse. The imaging sequence consists of a series of pulses transmitted through the main fiber to an identified site at selected intervals (e.g., 5 nanosecond). Each pulse generates a photon migration pattern which is received through an identified optical coupling fiber and is recognized by the central computer as originating from a certain receiving fiber or set of receiving fibers by time encoding. The transmitter pulse stimulates all transmit fibers in sequence. Similarly, the pattern received is a composite of all receiver positions. The imaging console "knows" not only the location of the fiber, but also identifies the signal received from the fiber conduit by its time sequence with respect to the synchronizing pulse. The transmission / reception algorithm consists of a sequence of excitation pulses followed by photon diffusion patterns detected at the particular positions selected specifically for the organ being studied.

The system may use a generic transmission / reception algorithm designed for an average organ or a patient specific algorithm. Furthermore, different algorithms may be used for ipsilateral, contralateral, *de novo* or recurrent brain bleeding. The optical coupler can be attached to the head (or any part of the body) for longer periods of time to monitor evolution of a tissue state (e.g., brain bleeding, compartment syndrome, or changes in a

stroke induced volume) during and after administration of a specific drug. For example, the system can also monitor evolution of a stroke induced volume or changes in intracranial pressure after administration of an osmotic agent (e.g., mannitol, glycerol), texamethasone (with its effects delayed for several hours) or another drug that temporarily reduces brain oedema. The system can also monitor evolution of a solute (e.g., glucose) as it equilibrates in the bloodstream.

Computer system 96 provides an overlay of the two images with contrast due to vascularity/vasculogenesis, blood vessels permeability, proliferation/degeneration of intracellular organelles, or some other tissue characteristics. To properly correlate the optical images to the NMR images, the optical images need to have an adequate contrast. The desired gradient of contrast is accomplished by selecting a suitable contrast agent (i.e., an exogenous pigment) and a wavelength of the introduced light. The spectrophotometer may construct separate images based on the scattering coefficient or the absorption coefficient. Furthermore, imaging center 95 may employ an amplitude modulation system or a CW system rather than the TRS system to increase resolution for some types of images.

In the case of brain examination, for instance, it is desired to detect and localize abnormal regions of 2 to 3 cm in diameter. This is the characteristic size of a hematoma or brain bleed which creates significant risk to the patient. One of the difficulties in employing spectrophotometric examination is the fact that the hair of a subject may be brushed in a certain way which accumulates more hair on one side than on the other. According to the invention, an optical coupler is provided having fibers that have freely protruding end portions of sufficient length to

penetrate the hair and enter between the hair follicles. In some instances, especially in the use of large optical fibers, it is practical to use fibers of the order of 32 in number, both for the source and detector, for the purposes of continuous wave (CW) examination.

In other cases, in particular when smaller fibers are employed, a much larger number of fibers is employed, for instance, as many as 1,000 in the case of fibers having a diameter of 0.1 or 0.2 mm.

Single mode fibers, which are characteristically small, are exceedingly effective light carriers for their size, and in some instances are preferred. In those cases especially, enlarged ends are provided on the fibers so that the fiber points do not cause irritation to the head or other examined portion of the patient. In some instances, lenses are also advantageously employed at the ends of the fibers to increase pick up of light when the fibers are employed as detecting fibers. In some instances, gradient index fibers which are self-focusing are used for collecting the light, the gradient index fibers extending either entirely to the detector or to a juncture where the light is transferred to a single mode or other transmitting fiber through an effective coupling medium.

According to the invention, it is realized that covering those fibers with protective disposable elements, to be disposable from patient to patient, will ensure a safe imaging condition and efficient use of the equipment.

The embodiments now to be described illustrate these and other features, and diagrammatically illustrate concepts employable for practical manufacture and use of the devices in spectrophotometric monitoring in the medical and home settings.

Referring to Figs. 3 and 3A, a handheld hairbrush optical coupler 10, has two groups of fibers 16 and 18 protruding from the under surface of the lower portion of the hairbrush 14. In one embodiment one group leads to a single light source and the other group leads to a single detector. Between the sections 16, 18 populated by fibers is a barrier 20 of conformable substance adapted to engage the surface and prevent travel of light directly along the surface from source to detector. In the embodiment shown, the groupings of fibers having length l of approximately 2 cm and a width w of 1 cm. The overall hairbrush has a length of about 10 cm and a width about 6 cm in the case where l_1 is 6 cm.

The design of the embodiment of Figs. 3 and 3A can be scaled for examination of tissue at different depths keeping in mind that the photon migration path of the scattering light from source to detector follows a banana-like probability configuration in which the mean depth is about one-half the source-to-detector spacing. In an embodiment suitable for hematoma detection where it is wished to examine tissue to a mean depth of approximately 3 cm, the distance l_1 between the centers of the source and detector groupings of fibers is approximately 6 cm. For shallower imaging, the distance l_1 is shortened. In certain embodiments, the fiber groupings 16 and 18 are made laterally adjustable along the length of the hairbrush handle, whereas in other instances different sizes of hairbrushes are employed for different l_1 spacings.

As is described in the literature and in the patent applications that have been incorporated by reference, a continuous wave spectrophotometer such as this, operating in the continuous wave manner, are useful as in a hematoma

monitor, and as a tumor detector and as trend indicators with respect to metabolic conditions such as the relationship between hemoglobin and oxyhemoglobin, with respect to blood sugar, and with respect to sodium and potassium metabolism.

There are conditions also in which a form of localization or imaging is achievable with CW depending upon the specific arrangement and nature of the processor employed with the continuous wave scheme.

The hairbrush shown in Figures 3 and 3A also has capability in other modes of spectrophotometric examination.

In all cases with respect to brain imaging, the invention proceeds from the realization that while brushed hair introduces irregularities hair follicles at the scalp are relatively evenly distributed symmetrically relative to the forward to back centerplane of the head. By having free-ended optical fiber portions small enough and of sufficient density to penetrate to the scalp and distribute and collect the needed light for spectrophotometric examination, the unbalancing factor of mode of hairbrushing or amount of hair present is eliminated and the spectrophotometric results are regularized. The melanin in the hair follicles still has influence upon the amount of light transferred but comparison of left to right or reference readings reduces the effect of that variable and produces a more useful examination.

The device of Fig. 3 and 3A is therefore useful in particular for lateral comparative reading as will be described further on.

Referring now to the embodiment of Figs. 4 and 4A, in this case a hairbrush presents an array of fibers in known position across the under surface of the hairbrush. Whereas individual fibers can be advantageously employed

both as source fibers for delivering light to the tissue and at a later time as detector fibers while other fibers deliver light to the tissue, in some cases it is preferred to have special purpose fibers. That is the arrangement shown in Figs. 4 and 4A. Light delivering or source fibers are indicated at 36a and detector fibers at 36b. Whereas a known location of the fibers is important, and a regular pattern is usually convenient, a regular pattern is not required. In fact to some extent there is a degree of irregularity in the pattern shown in Figure 3A. The controller and processor for this array system can be employed in known ways. A common way is to illuminate a single fiber or single local group of fibers that act as a single fiber at any one time, and to proceed through the array on that basis, while taking readings from all of the detector fibers or groups of detector fibers that act as a single detection fiber. The resulting data in digital form is assembled as a matrix and suitably processed. By examination of the matrix after scanning through the entire array, it is possible to generate a back projection image of the area examined. Use of such a hairbrush with PM or TRS (pulse) techniques can enhance the image produced.

The freely extending end portions of the fibers of the hairbrush are constructed to extend through the depth of hair that is present for the particular application. Typically this depth may range in length from between 1 and 2.5 cm, dictating a freely extending fiber portion of similar or somewhat greater length. The particular stiffness of the freely extending fiber portions is determined based upon factors such as the sensitivity of the patient (e.g., a different stiffness being appropriate for adults than for young children), as well as taking into account the particular modulus of elasticity of the fiber

material, (e.g., the modulus being different between glass and plastics), and the diameter and lengths of the fibers, and whether the fibers receive lateral support. These considerations determine the columnar properties of the individual fibers. Where the fibers are closely packed, and in particular, in the case of fine fibers, the degree of mutual support offered by neighboring fibers is taken into account in the selection of the parameters.

In general, the length/diameter ratio of the freely extending portions of the fibers from the hairbrush support or handle range between 5 and 200. A preferred range is between 20 and 150, and in a presently most preferred range, between about 50 and 125. The optical fibers have diameter of the order of 0.1 to 3 mm and in certain preferred conditions have a length between about 0.5 to 3 cm. In a particularly preferred region of selection, chosen for comfort, the fibers have a diameter of 0.2 to 0.5 mm and a length of about 1 to 2.5 cm.

In the simple instance of use of the imaging array of Figures 4 and 4A, using continuous wave spectrophotometric techniques, the fibers serving as source and the fibers serving as detection fibers are grouped to provide a four by four array resulting in 16 groupings of source and 16 groupings of detector fibers. Each group of source fibers is activated in turn for a period for example 16 seconds by the respective light source, which may be a conventional flashlight bulb. From this data, using analytical techniques described elsewhere, it is possible to define a back projection image that can be meaningful to determine presence of an occluding or unusual object such as a hematoma or breast tumor. Typically the controller and processor employed with this device have a memory and the hairbrush device itself is applied to a reference source. A

suitable reference is a symmetrical portion on the other side of the body, and another, a previous reading at an earlier time from the identical location on the body now being examined. A difference between measurement and reference indicates an abnormality that suggests either therapy or more accurate, more expensive imaging procedures such as an MRI examination. Thus such devices as shown in Figures 3 and 4 can serve to screen when to use more expensive MRI imaging techniques.

In Figure 5, three locations for the hairbrush of Fig. 3 are shown. The hairbrush placed on the left side may be used to produce reference data for the hairbrush placed on the right side of the head and vice versa. On the other hand, the hairbrush may simply be moved over the object of interest to observe differences that may have been caused by abnormalities, e.g., to monitor recurrence of hematoma.

Referring to Figure 6, in the case of use of hairbrushes as pictured in 4 and 4A, precise positioning is especially important to set a base line. The helmet has cutouts that are shaped as shown in 6B to receive the hairbrush 30, the cutout 44 being bounded by rigid sides 45 that serve as guides to precisely locate the hairbrush and guide it into engagement with the head, with the probes penetrating the free hair 42.

Figure 6A shows guiding the hairbrush into the precisely known position on the sides and the top of the head.

Figure 6 pictures diagrametrically a helmet or supporting structure with a chin strap that ensures the same position of the helmet from use to use. Not shown is a disposable, inflatable innerliner that adapts the helmet to different sizes and shapes of heads and locates the head in

the helmet in a predetermined way. Such liners may be disposable after each use.

The set of Figures 7 through 11 are diagrammatic representations of a hairbrush optical coupler. The handle of the hairbrush 66 comprises an upper part 62 and a lower part 64. The upper part of the handle is fixed to the fibers at least during use, and the lower part of the handle is slidable along the fibers as it moves together or apart from the upper part of the handle. In Figure 7 the parts are shown pushed together.

Freely extending fiber end portions 57 extend freely from the lower surface of the hairbrush, to penetrate the hair with the advantages that have been described. The fibers are shown to extend through the hairbrush at the top but in practice the fibers are gathered and taken by cable to the respective device such as the hematoma monitor, tumor detector or imager as described above. While the fibers are shown to be distributed uniformly, as would be the case with the imaging hairbrush shown in Figures 4 and 4A, they can be grouped in accordance with Figure 3 or put in other arrangements as may be desired.

The purpose of Figures 7 through 11 is to illustrate in a general way the concept that protective covers may be applied to fibers and then removed and replaced from patient to patient. Likewise the hairbrush itself may be constructed to be sterilized as in a gas autoclave.

Referring to Figure 7, as mentioned the ends of the fiber portions 57 extend below the hairbrush for a length suitable to penetrate the hair and reach the scalp. In the case the brush is used to achieve conformability and comfort against say the breast or a limb or the torso of the body, the length of the free end portions of the fibers is selected to perform that function.

Figure 8 is a first step in the sequence to apply protectors to the ends of the fibers. The lower portion 64 of the hairbrush handle is lowered to the ends of the fibers, sliding on guides 66 permanently mounted on the upper portion 62 of the hairbrush.

In the position of Figure 8, the fiber ends are flush with the lower surface of the hairbrush handle. As illustrated in Figure 9, a sleeve dispenser, also pictured at the lower part of Figure 11, is then brought into registry with suitable guides on the hairbrush such that its dispensing surface is aligned with the lower surface of the hairbrush and protector-carrying cavities within the dispenser are precisely aligned with the fibers. This is made possible by guides 67 on the dispenser that engage appropriate grooves on the brush.

The dispenser 65 is comprised of a main body which, in the magnified views of Figures 9A through 11A, is seen to define cavities 59' in which protective sleeves 59 are placed. As shown in Figure 9, the dispensing face of the dispenser is brought face to face with the lower surface of the handle portion 64. The fibers 57 align precisely with the hollow spaces of the sleeves 59, the fiber ends 57 being shown flush with the lower part of handle 64 in Figure 9A.

As shown also in Figure 9A, the length of the sleeves is for instance of the order of five times the diameter of the fibers. The particular length depends upon how much length of the fibers is desired to be covered, which also may depend e.g., upon other means of cleaning or sterilization to be employed.

In important instances, not shown, the end sleeves extend the full length of the fibers and are integral with cover portions that cover the bottom of the hairbrush. The

dispenser is effective in that case to apply the entire cover to the hairbrush.

Returning to Figure 9, in the position shown, the dispenser is engaged with the hairbrush while the hairbrush lower part is spaced away the from upper part. The position is determined by a stop provided by slide 66 protruding from the top portion of the hairbrush, that limits the travel of the lower portion to achieve a flush or slightly withdrawn condition. After the relationship of Figure 9 is achieved, the upper portion of handle 62 is moved downwardly to engage the lower portion of the handle to the position shown in Figure 11. Since the upper portion of the handle is fixed to the fibers, the fibers are thus carried forward, sliding in the lower portion of the handle, and the free ends of the fibers emerge from the lower part of the handle and enter the sleeves in the dispenser as depicted in Figure 10. In case the fibers do not have sufficient columnar stiffness, tubular guides are employed between the upper and lower handle portions, one for each fiber, to prevent columnar collapse of the fibers and to ensure the sliding action just described.

At this point the end portions of the fibers have entered the protective sleeves. The lower portion of the dispenser comprises an activating bar 63 that is connected to a set of ejector pins, one associated with each of the sleeves within the dispenser. Compression springs 69 maintain the ejector bar in its lower position as shown in Figures 9 and 10. Upon depression of the ejector bar from the position of Figure 10, the ejector pins engage the ends of the fibers and their sleeves and effectively push the protected end portions out of the dispenser to the position shown in Figure 9. After this position is achieved, the ejector bar 63 collapsed against the lower portion of the

dispenser, as shown in Figure 11, is released with the springs 69 returning to the dotted line position shown in Figure 11. The hairbrush as shown in Figure 9 has freely extending fiber end portions housed in protective sleeves 59 and arranged to enter the head of hair or otherwise serve the functions that have been described.

In a preferred embodiment the sleeves are translucent teflon suitable to match with the substance of the skin to transfer light from source fibers to the head and detector fibers to transfer the light to the detector.

These sleeves are disposable and can be ejected. By moving the lower handle portion from the position in Figure 9 to the position of Figure 8, the lower part of the hairbrush handle strips the sleeves from the fibers which are discarded. Then, with the return of the handle position from the spaced apart position shown in Figure 8, the condition of Figure 7 is reachieved.

In certain instances it is unnecessary to have the fibers covered. In that case the device as shown in Figure 7 can be used directly.

Figures 12, 13, and 14 illustrate alternate preferred forms of protective sleeves for the optical fibers. In Figure 12 near the end of the fiber a socket S is provided in the substance of the protective cover 59a into which a suitably shaped contrast element can be inserted. Referring to Figure 12A a contrast element vial V contains aqueous copper sulfate solution 112, which is a suitable contrast agent for MRI. The vial is of flexible material and can be deformed and inserted into the socket S shown in Figure 12. In Figure 12B sponge rubber ball R" is shown, suitable as a contrast agent for acoustic imaging. An insert of solid sodium iodide crystals is appropriate for xray. Different protective sleeves can be provided having

different contrast agents, to enable dual mode examination, for instance with MRI or acoustic imaging. Other contrast agents for other modes of examination can be used.

Another feature of the embodiment of Figure 12 is the annular end portion E of the sleeve which protrudes below the crossing plate that closes the bottom of the protective cavity formed by sleeve 59a. The optical fiber 57 is intended to extend the full length of that cavity and engage the bottom of the cavity, to be immersed in an optional optical matching fluid having the same refractive index as the fiber and the sleeve, to avoid a change of refractive index that can occasion light loss. The annular end portion E serves as a light dam or barrier. In the case that the material of the sleeve is uniformly translucent, an outer black coating or other means of achieving opacity is provided about the end tips. As the fiber is pressed against the tissue, the end tip E indents the fiber and creates an optical dam that prevents lateral movement of light and thus prevents false signal traveling along the engaged surface from reaching the detector. This arrangement prevents emission of such light when used on light source fibers: it also has utility for imaging fibers in the case of exposure to ambient light that may confound the measurement.

In the embodiment of Figure 13 the substance of the tubular sleeve 59b is an opaque elastomer. The ends E' serve the function of the ends E in Figure 12 and the cross member shown but not labeled in Figure 13 serves to form the bottom cap and protect the fiber from contaminating conditions. The outer wall of the sleeve 59b is provided with a recess R' into which a contrast ring shown in Figure 13A can be inserted. Figure 13B illustrates a cross section of such a contrast ring, element R, of sponge rubber to

serve as a contrast agent for acoustic imaging. In Figure 13C the ring is hollow and has copper sulfate in aqueous solution contained by fluid impermeable walls 110 of the ring. Again, the ring can contain sodium iodide crystals. In Figure 14 another preferred embodiment of the sleeve is shown in which instead of a plain plate forming the bottom of the elastomeric sleeve, a lens L is employed for the advantage of collecting additional light for transmission up the fiber. In the preferred embodiment of Figure 14, the terminal end of the fiber is enlarged to provide sufficient area contact to provide comfort to the patient. The form is particularly useful with small or stiff fibers which have a tendency to produce pain. In other embodiments. instead of a separable element, the fibers themselves are configured to have enlarged end portions, for instance balls formed by melting the ends for achieving comfort. In such cases, the fibers are advantageously provided with an outer coating e.g. titanium dioxide paint or other pigment to achieve a diffusing condition to facilitate the transfer of light.

Referring to Fig. 15, a breast examination system is shown employing brushes 150, 160 and 150' and 160'. The brushes are defined by a comfortable mass of free ended fibers that conform to the breast and transmit light in a desirable way. As shown the fibers extend across the entire base of the brush, however fibers arranged as in Figures 3 and 3a may also be employed. In each case, the signals from the relative symmetrical left and right inner breast surfaces are taken to bilateral comparator 162 whereas the similar signals from the outer surfaces of the left and right breasts, from detectors 150, 150', are taken to bilateral comparator 152. By further processing (not shown), the results of the two comparisons may be also correlated to further elaborate the examination.

Referring to Fig. 16, a comfortable brassier like breast examination device is shown. In practice, it is possible to employ a transverse band of fibers, but in other instances the hemispherical surface of the brassier is entirely populated by the fibers in an array such as generally suggested in Figure 4A. The brassier-like device is applied in the same way each time and enables the position from measurement to measurement to be accurately known so that comparison to a base-line condition can be made. Even without such reference, the examination is useful to determine presence of an inhomogene to identify a condition that requires further diagnosis. For daily monitoring, contrast agent is not suggested for use in this examination of breast tissue. In the event monitoring suggests a problem, a contrast agent may be administered to more effectively examine the tissue spectrophotometrically, or examination by another modality, though much more costly, may then be indicated.

In the case of the brassier or helmet it is advantageous to mold a suitable thermoplastic that softens at comfortable temperature, about the object to be examined, and when cooling, to use that form either directly as a guide to bring a hairbrush or other monitoring device into position for repetitive readings.

What is claimed is: